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Docket Number: 037003-0275470PATENT APPLICATION

Client Reference: 1997-30-0565CP1



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re The Application of REFF et al.

Group Art Unit: 1644

Application No.: 09/019,441

Examiner: P. Huynh

Filed: February 5, 1998

Confirmation No.: 2038

For: GAMMA-1 AND GAMMA-3 ANTI-HUMAN CD23 MONOCLONAL ANTIBODIES  
AND USE THEREOF AS THERAPEUTICSINFORMATION DISCLOSURE STATEMENTCommissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Pursuant to 37 C.F.R. §1.56, the attention of the Patent and Trademark Office is hereby directed to the references listed on the attached PTO-1449. Unless otherwise indicated herein, one copy of each reference is attached. The attached references were cited in U.S. and international/foreign patent applications related to the present application. It is respectfully requested that the listed references be expressly considered during the prosecution of this application, and that the references be made of record therein and appear among the "References Cited" on any patent to issue there from.

Pursuant to 37 C.F.R. §1.97(b)(4), this Information Disclosure Statement is being filed before the mailing of a first office action on the merits after the filing of a request for continued examination under 37 C.F.R. § 1.114.

It is believed that no fee is required for this submission. Please credit or debit Deposit Account 033975 as needed to ensure consideration of the disclosed information.

Respectfully Submitted,

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Date: November 6, 2003

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FORM PTO-1449 (modified)  
To: U.S. Department of Commerce  
(PW FORM PAT-1449)  
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# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

Atty. Dkt. No.	M#	Client Ref.
	0275470	1997-30-0565CP1
Applicant: REFF <i>et al.</i>		
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Filing Date: February 5, 1998		
Examiner: P. Huynh		Group Art Unit: 1644

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## U.S. PATENT DOCUMENTS

Examiner's Initials*	Document Number	Date MM/YYYY	Name (Family Name of First Inventor)	Class	Sub Class	Filing Date
	AR 4,975,369	12/1990	Beavers et al.			
	BR 5,648,267	07/1997	Reff			
	CR 5,736,137	04/1998	Anderson			
	DR 5,811,524	09/1998	Brams et al.			

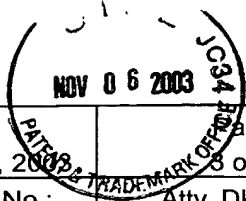
## FOREIGN PATENT DOCUMENTS

	Document Number	Date MM/YYYY	Country	Inventor Name	English Abstract	Translation Readily Available
	ER WO 89/00138	01/1989	WIPO	Gunnar Strömberg		
	FR WO 92/17707	10/1992	WIPO	Tanox Biosystems Inc.		
	GR WO 93/02108	02/1993	WIPO	IDEC Pharmaceuticals Inc.		
	HR WO 96/12742	05/1996	WIPO	Glaxo Group Ltd.		

## OTHER

✓	IR	Luo et al., "Cross-linking of CD23 antigen by its natural ligand (IgE) or by anti-CD23 antibody prevents B lymphocyte proliferation and differentiation", J. Immunol., 146(7):2122-9 (1991).				
✓	JR	Groves et al., "Production of an ovine monoclonal antibody to testosterone by an interspecies fusion", Hybridoma, vol. 6(1):71 (1987).				
•	KR	Robbins, Pathologic Basis of Disease, 5th Ed., ed. by Cotran et al., W.B. Saunders Co., Philadelphia, PA, 1994, pp. 197-199.				
•	LR	Seaver, Genetic Engineering News, 14(14): pp. 19, 21 (Aug., 1994).				
•	MR	Haak-Frendscho et al., "Administration of an anti-IgE antibody inhibits CD23 expression and IgE production in vivo", Immunology, 82:306 (1994).				
•	NR	Delespesse et al., "Human IgE-binding factors", Immunology Today 10:159, (1989).				
•	OR	Durum et al., "Proinflammatory Cytokines and Immunity," in Fundamental Immunology, Third Edition, Chapter 21, ed. by Paul et al., Raven Press, Ltd., New York, p. 826 (1993).				
•	PR	Vercelli et al., "Induction of human IgE synthesis requires interleukin 4 and T/B cell interactions involving the T cell receptor/CD3 complex and MHC class II antigens", J. Exp. Med., 169:1295 (Apr. 1989).				
•	QR	Presta et al., "Humanization of an antibody directed against IgE", J. Immunology, 151(5):2623 (Sep. 1993).				
•	RR	Strike et al., "Production of human-human hybridomas secreting antibody to sheep erythrocytes after in vitro immunization", J. Immunol., 132(4): 1798 (Apr. 1984).				
•	SR	Cruse et al., Illustrated Dictionary of Immunology, CRC Press, Boca Raton, Fla., 1995, p. 69.				
•	TR	Capon et al., "Designing CD4 immunoadhesins for AIDS therapy", Nature, 337:525 (Feb. 1989).				
•	UR	Rector et al., "Detection and characterization of monoclonal antibodies specific to IgE receptors on human lymphocytes by flow cytometry", Immunol., 55: 481-488 (1985).				
•	VR	Suemura et al., "Monoclonal anti-Fc epsilon receptor antibodies with different specificities and studies on the expression of Fc epsilon receptors on human B and T cells", J. Immunol., 137: 1214-1220 (1986).				
	WR	Noro et al., "Monoclonal antibody (H107) inhibiting IgE binding to Fc epsilon R(+) human lymphocytes", J. Immunol., 137: 1258-1263 (1986).				
	XR	Yu et al., "Negative feedback regulation of IgE synthesis by murine CD23", Nature, 369: 753-756 (1994).				

INFORMATION DISCLOSURE STATEMENT BY APPLICANT		Date: November 5, 2003	Page 2 of 3	Applicant: REFF et al.	Appln. No.: 09/019,441
OTHER (Continued)		Client Ref. No.: 997-30-0565CP1	Atty. Dkt. No.: 037003-0275470	Examiner: P. Huynh	Group Art Unit: 1644
YR	Bonnefoy et al., "Regulation of IgE synthesis by CD23/CD21 interaction", Int. Arch. Allergy Immunol., 107: 40-42 (1995).				
ZR	Aubry et al., "CD21 is a ligand for CD23 and regulates IgE production," Nature, 358:505-507 (1992).				
AAR	Bonnefoy et al., "Receptors for IgE", Curr. Opin. Immunol., 5: 944-949 (1993).				
BBR	Grosjean et al., "CD23/CD21 interaction is required for presentation of soluble protein antigen by lymphoblastoid B cell lines to specific CD4+ T cell clones", Eur. J. Immunol., 24: 2982-2988 (1994).				
CCR	Pene et al., "Interleukin 5 enhances interleukin 4-induced IgE production by normal human B cells. The role of soluble CD23 antigen", Eur J. Immunol., 18: 929-935 (1988).				
DDR	Saxon et al., "Soluble CD23 containing B cell supernatants induce IgE from peripheral blood B-lymphocytes and costimulate with interleukin-4 in induction of IgE", J. Allergy Clin. Immunol., 86 (3 pt 1) 333-344 (1990).				
EER	Hassner and Saxon, "Isotype-specific human suppressor T cells for IgE synthesis activated by IgE-anti-IgE immune complexes", J. Immunol., 132: 2844 (1984).				
FFR	Carroll et al., "Mouse x human heterohybridomas as fusion partners with human B cell tumors", J. Immunol. Methods 89: 61 (1986).				
GGR	Boerner et al., "Production of antigen-specific human monoclonal antibodies from in vitro-primed human splenocytes", J. Immunol., 147: 86 (1991).				
HHR	Bourget et al., "CD20 monoclonal antibodies decrease interleukin-4-stimulated expression of the low-affinity receptor for IgE (Fc epsilon RII/CD23) in human B cells by increasing the extent of its cleavage," Eur. J. Immunol., 25(7):1872-76 (1995).				
IIR	Bonnefoy et al., "A new role for CD23 in inflammation", Immunol. Today, 17(9): 418-20 (1996).				
JJR	Plater-Zyberk et al., "Marked amelioration of established collagen-induced arthritis by treatment with antibodies to CD23 in vivo" Nature Medicine, 1(8):781-785 (1995).				
KKR	The Merck Manual, 16 <sup>th</sup> Edition, Berkow, R. ed., Rahway, NJ, pp. 1305-12 and 1334-8 (1992).				
LLR	Busse et al., "Results of a Phase I, Single-dose, Dose-escalating Trial of a Primatized Anti-Cd23 Monoclonal Antibody (IDEC-152) in Patients With Allergic Asthma," J. of Allergy and Clinical Immunol., 107(2): abstract no. 354 (Feb. 2001).				
MMR	Nakamura et al., "In vitro IgE inhibition in B cells by anti-CD23 monoclonal antibodies is functionally dependent on the immunoglobulin Fc domain", Intl. J. of Immunopharmacol., 22:131-41 (2000).				
NNR	Bettler et al., "Binding site for IgE of the human lymphocyte low-affinity Fcε receptor (Fc εRII/CD23) is confined to the domain homologous with animal lectins", Proc. Natl. Acad. Sci., USA, 86:7118-22 (1989).				
OOR	Webster's II New Riverside University Dictionary, Houghton-Mifflin Co., Boston, p. 933 (1984).				
PPR	Yoshikawa et al., "Soluble FcεRII/CD23 in patients with autoimmune diseases and Epstein-Barr virus-related disorders: analysis by ELISA for soluble FcεRII/CD23", Immunomethods, 4(1):65-71 (Feb. 1994).				
QQR	Muino et al., "The importance of specific IgG and IgE autoantibodies to retinal S antigen, total serum IgE, and sCD23 levels in autoimmune and infectious uveitis", J. Clin. Immunol., 19(4):215-222 (Jul. 1999).				
RRR	Soh et al., "IgE and its related phenomena in bullous pemphigoid", Br. J. Dermatol., 128:371-377 (1993).				
SSR	Fries et al., "Monocyte receptors for the Fc portion of IgG studies with monomeric human IgG1: normal in vitro expression of Fcγ receptors in HLA-B8/Drw3 subjects with defective Fcγ-mediated in vivo clearance", J. Immunol., 129: 1041-1049 (1982).				
TTR	Kurlander and Batker et al., "The binding of human immunoglobulin G1 monomer and small, covalently cross-linked polymers of immunoglobulin G1 to human peripheral blood monocytes and polymorphonuclear leukocytes", J. Clin. Invest., 69: 1-8 (1982).				
UUR	Woof, "The monocyte binding domain(s) on human immunoglobulin G", Mol. Immunol., 21:523-527 (1984).				
VVR	Burton and Woof, "Human antibody effector function", Human Antibody Effector Function, Adv. Immunol., 51: 1-84 (1992).				
WWR	Karas et al., "Characterization of the IgG-Fc receptor on human platelets", Blood, 60:1277-1282 (1982).				



<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>		Date: November 5, 2003	Page 8 of 3	Applicant: REFF et al.	Appln. No.: 09/019,441
<b>OTHER (Continued)</b>		Client Ref. No.: 1997-30-0565CP1	Atty. Dkt. No.: 037003-0275470	Examiner: P. Huynh	Group Art Unit: 1644
	XXR	Van de Winkel and Anderson, "Biology of human immunoglobulin G Fc receptors", J. Leuk. Biol., 49:511-524 (1991).			
	YYR	Huizinga et al., "Binding characteristics of dimeric IgG subclass complexes to human neutrophils", J. Immunol., 142:2359-2364 (1989).			
	ZZR	Bosma et al., "A severe combined immunodeficiency mutation in the mouse", Nature, 301:527 (1983).			
	AAAR	Mosier et al., "Transfer of a functional human immune system to mice with severe combined immunodeficiency", Nature, 335:256 (1988).			
	BBBR	Mosier et al., "Immunodeficient mice xenografted with human lymphoid cells: new models for in vivo studies of human immunobiology and infectious diseases", J Clin Immunol., 10:185-91 (1990).			
	CCCR	Abedi et al., "Immunoglobulin production in severe combined immunodeficient (SCID) mice reconstituted with human peripheral blood mononuclear cells", Eur. J. Immunol., 22:823 (1992).			
	DDDR	Mazingue et al., "Obtention of a human primary humoral response against schistosome protective antigens in severe combined immunodeficiency mice after the transfer of human peripheral blood mononuclear cells", Eur. J. Immunol., 21:1763 (1991).			
	EEER	Kilchherr et al., "Regulation of human IgE response in hu-PBL-SCID mice", Cellular Immunology, 151:241 (1993).			
	FFFR	Spiegelberg et al., "Role of interleukin-4 in human immunoglobulin E formation in hu-PBL-SCID mice", J. Clin. Invest., 93:711 (1994).			
	GGGR	Carballido et al., "IL-4 induces human B cell maturation and IgE synthesis in SCID-hu mice. Inhibition of ongoing IgE production by in vivo treatment with an IL-4/IL-13 receptor antagonist", J. Immunol., 155:4162 (1995).			
	HHHR	King et al., "Expression, purification and characterization of a mouse-human chimeric antibody and chimeric Fab' fragment", Biochem. J., 281:317-23 (1992).			
	IIIR	Queen et al., "A humanized antibody that binds to the interleukin 2 receptor", Proc. Nat. Acad. Sci. USA, 86:10029 (1989).			
	JJJR	Love et al., "Recombinant antibodies possessing novel effector functions", Methods Enzymol., 178:515-27 (1989).			
	KKKR	Hutzell et al., "Generation and characterization of a recombinant/chimeric B72.3 (human $\gamma_1$ )", Cancer Res., 51:181 (1991).			
	LLLR	Chiang et al., "Direct cDNA cloning of the rearranged immunoglobulin variable region", Biotechniques, 7(4):360-6 (1989).			
	MMMR	Heinrich et al., "Characterization of a human T cell-specific chimeric antibody (CD7) with human constant and mouse variable regions", J. Immunol., 143:3589 (1989).			
	NNNR	Hardman et al., "Generation of a recombinant mouse-human chimaeric monoclonal antibody directed against human carcinoembryonic antigen", Int. J. Cancer, 44:424 (1989).			
	OOOR	Orlandi et al., "Cloning immunoglobulin variable domains for expression by the polymerase chain reaction", Proc. Nat. Acad. Sci. USA, 86(10):3833-7 (1989).			
	PPPR	Norman et al., "Reversal of Acute Allograft Rejection With Monoclonal Antibody," Transpl. Proc., 17:39-41 (1985).			
	QQQR	Sarfati et al., "Elevation of IgE-binding factors in serum of patients with B cell-derived chronic lymphocytic leukemia", Blood, 71:94-98 (1988).			
	RRRR	Saragovi et al., "Design and synthesis of a mimetic from an antibody complementarity-determining region", Science, 16:253(5021):792-5.			
Examiner			Date Considered:		
<b>*EXAMINER:</b> Initial if citation considered, whether or not citation is in conformance with MPEP § 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.					